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Department of Health and Human Services
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, MA 02180
Phone: (781) 279-1675
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WARNING LETTER
NWE-09-99W

February 12, 1999

Certified Mail
Return Receipt Requested

Mehdi Abedi, M.D.
Capitol Imaging Group
6 Blackstone Valley Place
Lincoln, RI 02865

Dear Dr. Abedi,

We are writing to you because on February 12, 1999, your facility was inspected by a representative of the State of Rhode Island, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 findings at your facility:

Level 1: The interpreting physician did not meet the requirement of being licensed by a State to practice medicine: [redacted]

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

In addition, your response should address the Level 2 findings that were listed on the Facility Inspection Report, which was issued to your facility at the close of the inspection. These Level 2 findings are:

Level 2: The interpreting physician did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography: [redacted]

Level 2: The interpreting physician did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period): [redacted]

Level 2: The interpreting physician did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period: [redacted]

Level 2: The interpreting physician did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period: [redacted]

Level 2: The interpreting physician did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period: [redacted]

Level 2: The radiological technologist did not meet the continuing education requirement of having completed a min. of 15 CEUs in mammography in a 36 month period: [redacted]

Level 2: The interpreting physician did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period: [redacted]

Level 2: The interpreting physician did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period: [redacted]

The specific Level 2 problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Michael J. Leal
MQSA Auditor
U.S. Food and Drug Administration
120 Front Street, Suite 680
Worcester, MA 01608

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Leal at (508) 793-0422.

Sincerely yours,

John R. Marzilli
District Director
New England District Office